UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/852,100 | 05/09/2001 | Bradley A. Ozenberger | AHP 98126 P2 | 4733 |

25291 7590 08/18/2003

WYETH
PATENT LAW GROUP
FIVE GIRALDA FARMS
MADISON, NJ 07940

| EXAMINER | |
|---|---|
| NICHOLS, CHRISTOPHER J | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1647 | |

DATE MAILED: 08/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Applicati n No. | Applicant(s) | |
|---|---|---|---|
| | 09/852,100 | OZENBERGER ET AL. | |
| | Examin r | Art Unit | |
| | Christopher Nichols, Ph.D. | 1647 | |

*-- The MAILING DATE of this communication app ars on the cover sh et with the correspondence address --*

**Period f r Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *23 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-33* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims **1-3**, drawn to a *polynucleotide* comprising an endogenous variant of the nucleotide sequence of SEQ ID NO: 1, classified in class 536, subclass 23.1, for example.

II. Claims **4-9**, drawn to a *protein* comprising the amino acid sequence of SEQ ID NO: 2, classified in class 530, subclass 300, for example.

III. Claims **10-11** and **20**, drawn to a method for determining a polynucleotide encoding a β-amyloid peptide-binding protein (BBP) in a sample comprising *probes which hybridize to SEQ ID NO: 1*, classified in class 435, subclass 6, for example.

IV. Claims **12-15**, drawn to an *antibody* that binds specifically to a polypeptide comprising the amino acid sequence of SEQ ID NO: 1, classified in class 530, subclass 387.1, for example.

V. Claims **16-17**, drawn to a method for detecting a sample in a polypeptide comprising a region at least 90% identical to the amino acid sequence of SEQ ID NO: 2, said method comprising incubating a sample with a *reagent that binds specifically to said polypeptide*, classified in class 435, subclass 500, for example.

VI. Claims **18-19**, drawn to a method for *diagnosing a disease* characterized by aberrant expression of human β-amyloid peptide, comprising incubating a sample indicative of the aberrant expression of human β-amyloid peptide with a reagent

comprising a polypeptide comprising a region of at least 90% identical to the amino acid sequence of SEQ ID NO: 2, classified in class 435, subclass 7.1, for example.

VII. Claims **21-22**, drawn to a *method for identifying compounds* which regulate the activity of a β-amyloid peptide binding protein, classified in class 435, subclass 500, for example.

VIII. Claim **23**, drawn to a *method for the treatment* of a patient having need to inhibit β-amyloid peptide accumulation in the brain comprising administering to the patient a therapeutically effective amount of BBP1, classified in class 514, subclass 2, for example.

IX. Claim **24**, drawn to a *method for the treatment* of a patient having need to inhibit β-amyloid peptide accumulation in the brain comprising administering to the patient a therapeutically effective amount of an antibody which binds to an extracellular portion of BBP1, classified in class 424, subclass 130.1, for example.

X. Claims **25-31**, drawn to a *transgenic or chimeric nonhuman animal* comprising the polynucleotide of SEQ ID NO: 1, classified in class 800, subclass 8, for example.

XI. Claims **32-33**, drawn to a method for inhibiting expression of the BBP1 gene comprising antisense nucleic acid, classified in class 536, subclass 24.5, for example.

2. The inventions are distinct, each from the other because of the following reasons:

3. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions III, V, VI, VII, VIII, IX, and XI are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention III requires search and consideration of probes which hybridize to SEQ ID NO: 1, which is not required by any of the other Inventions. Invention V requires search and consideration of determining the presence or amount of a polypeptide in a sample, which is not required by any of the other Inventions. Invention VI requires search and consideration of diagnosing a disease, which is not required by any of the other Inventions. Invention VII requires search and consideration of method of identifying compounds, which is not required by any of the other Inventions. Invention VIII requires search and consideration of using BBP1 as a therapeutic agent, which is not required by any of the other Inventions. Invention IX requires search and consideration of using an anti-BBP1 antibody as a therapeutic agent, which is not required by any of the other Inventions. Invention XI requires search and consideration of antisense agents, which is not required by any of the other Inventions.

4. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Inventions I, II, IV, and X are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. The polynucleotide of Invention I can be used in materially different processes other

than to make the protein of Invention II, the antibody of Invention IV, or the nonhuman transgenic animal of Invention X, such in gene therapy or as a probe in nucleic acid hybridization assays. The protein of Invention II can be prepared by processes which are materially different from polynucleotide of Invention I, use of the antibody of Invention IV, or production via the nonhuman transgenic animal of Invention X, such as by chemical synthesis, or by isolation and purification from natural sources. While the antibody of Invention IV can be used to obtain the polynucleotide of Invention I and the protein of Invention II, it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods. The nonhuman transgenic animal of Invention X is not required to make or use the antibody of Invention X. The nonhuman transgenic animal of Invention X does not require the protein of Invention II or the antibody of Invention IV to be made or used. While the polynucleotide of Invention I can be used to make the nonhuman transgenic animal of Invention X, it can be made through materially different methods such as animal husbandry or mutagenesis of embryos.

5. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide of Invention I can be used to make the nonhuman transgenic animal of Invention X.

6. Inventions II and each of Inventions V, VI, VII, and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can

be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein of Invention II can be used to isolated β-amyloid for biochemical assays.

7. Inventions IV and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Invention IV can be used to isolate the protein of Invention II for biochemical assays.

8. Inventions I and each of V, VI, VII, VIII, IX, and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions I and each of V, VI, VII, VIII, IX, and XI are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions V, VI, VII, VIII, IX, and XI do not recite the use or production of the *polynucleotide* of Invention I.

9. Inventions II and each of III, IX, and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions II and each of V, VI, VII, VIII, IX, and XI are unrelated product and methods, wherein each is not required, one for another. For example, the

claimed methods of Inventions V, VI, VII, VIII, IX, and XI do not recite the use or production of the *protein* of Invention II.

10. Inventions IV and each of III, VI, VII, VIII, and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions IV and each of III, VI, VII, VIII, and XI are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions III, VI, VII, VIII, and XI do not recite the use or production of the *antibody* of Invention IV.

11. Inventions X and each of III, V, VI, VII, VIII, IX, and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions X and each of III, V, VI, VII, VIII, IX, and XI are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions III, V, VI, VII, VIII, IX, and XI do not recite the use or production of the *nonhuman transgenic animal* of Invention X.

12. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

13. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search

requirements, and/or different classification, restriction for examination purposes as indicated is proper.

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

## *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:00AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary L. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

CJN
August 15, 2003